



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply.

EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 2, 1999

MEMORANDUM

SUBJECT: **Product Chemistry Chapter for the Malathion Reregistration Eligibility Decision (RED) Document.**
DP Barcode No.: D256522
Chemical No.: 057701
Reregistration Case No.: 0248

FROM: William O. Smith, Chemist
Chemistry and Exposure Branch I
Health Effects Division [7509C]

THROUGH: F. B. Suhre, Branch Senior Scientist
Chemistry and Exposure Branch I
Health Effects Division [7509C]

TO: Paula Deschamp
Reregistration Branch II
Health Effects Division [7509C]

Attached is the Product Chemistry Chapter for the Malathion RED Document. This document was prepared by Dynamac Corporation under the supervision of HED and revised by the Chemistry & Exposure Branch to reflect Agency policies.

Attachment: Product Chemistry Chapter for the Malathion RED Document.

cc: P. Poli (SRRD), WSmith (CEB1), Malathion Reg. Std. File.
7509C:CEB1:WSmith:Rm 810C:CM2: 703-305-5353: 6/02/99.

MALATHION
Shaughnessy No. 057701; Case 0248

Reregistration Eligibility Decision
Product Chemistry Considerations

July, 9 1997

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

MALATHION

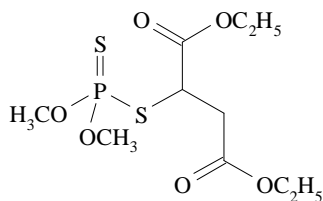
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 057701; Case No. 0248

DESCRIPTION OF CHEMICAL

Malathion [O,O-dimethyl dithiophosphate of diethyl mercaptosuccinate] is an insecticide used on a variety of vegetables, fruits, and field crops.



Empirical Formula:	C ₁₀ H ₁₉ O ₆ PS ₂
Molecular Weight:	330.4
CAS Registry No.:	121-75-5
Shaughnessy No.:	057701

IDENTIFICATION OF ACTIVE INGREDIENT

Malathion is a colorless to amber liquid with a mercaptan odor and boiling point of 156-157 C. Malathion is soluble in water at 145 ppm at 25 C. Malathion is readily soluble in most alcohols, esters, aromatic solvents, and ketones, and is only slightly soluble in aliphatic hydrocarbons.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/27/97 identified ten malathion manufacturing-use products (MPs) registered under Shaughnessy No. 057701, which are listed in Table 1. Only the registered malathion MPs listed in Table 1 are subject to a reregistration eligibility decision.

Table 1. Registered Manufacturing-use Products of Malathion.

Formulation	EPA Reg. No.	Registrant
95% T ^{1,2}	228-274	Riverdale Chemical Company
95% T ²	655-310	Prentiss Incorporated
25% FI	655-79	
45% FI ³	769-783	Sureco Incorporated
95% T	4787-5	Cheminova Agro A/S
95% T ^{2,4}	4787-24	
91% T ^{2,5}	5481-210	Amvac Chemical Corporation
95% T ²	10163-152	Gowan Company
95% T ²	19713-402	Drexel Chemical Company
95% T ²	51036-129	Micro-Flo Company

^a Transferred from Falls Chemicals Inc. (EPA Reg. No. 40831-110).

² Repackaged from an EPA-registered product.

³ Transferred from Southern Mill Creek Products (EPA Reg. No. 6720-346).

⁴ Transferred from American Cyanamid Company (EPA Reg. No. 241-77).

⁵ Transferred from Agrimont S.P.A. (EPA Reg. No. 43981-2).

REGULATORY BACKGROUND

The Science Chapter of the Malathion Reregistration Standard dated 7/31/87 and the Malathion Guidance Document dated 2/88 required updated product chemistry data for the malathion MPs.

In addition, product chemistry data were submitted concerning six putative impurities of malathion which were identified by the HED Metabolism Committee as being of potential toxicological concern (CBRS No. 9910, D178475, 6/16/92, R. Perfetti). The data indicated that three of these impurities were not present in technical malathion, and that one impurity is a minor impurity in technical malathion which is much less stable than malathion under field conditions. The two remaining impurities involved toxicological considerations and were referred to the TOX Branch.

The current status of the product chemistry data requirements for the malathion MPs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Most pertinent data requirements are satisfied for the Cheminova 95% T (EPA Reg. No. 4787-5); additional data are required concerning physical/chemical characteristics (OPPTS 830.7050,

830.7220, and 830.7950). All product-specific product chemistry data requirements are outstanding for the Prentiss 25% FI (EPA Reg. No. 655-79), which is formulated from an EPA-registered product. All product chemistry data requirements are outstanding for the Sureco 45% FI (EPA Reg. No. 769-783), which is apparently formulated from an end-use product. Data requirements for the seven repackaged products (EPA Reg. Nos. 228-274, 655-310, 4787-24, 5481-210, 10163-152, 19713-402, and 51036-129) will be satisfied by data for the technical source product(s). Provided that the registrants submit the data required in the attached data summary tables for the 95% and 91% Ts, and 45% and 25% FIs, and either certify that the suppliers of beginning materials and the manufacturing processes for the malathion MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, CBRS has no objections to the reregistration of malathion with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 7469
Subject: Response to the Malathion Reregistration Standard: Product Chemistry Data.
From: R. Perfetti
To: R. Engler and L. Rossi
Dated: 3/28/91
MRID(s): 40335801, 40944101-40944108, 40966602, and 40966603

CBRS No(s).: 9752
DP Barcode(s): D177109
Subject: Response to the Malathion Reregistration Standard: Product Chemistry Data.
From: R. Perfetti
To: W. Burnam and L. Rossi
Dated: 6/16/92
MRID(s): 42265301 and 42265302

CBRS No(s): 9910
DP Barcode(s): D178475
Subject: Malathion Reregistration: The Residue To Be Regulated.
From: R. Perfetti
To: W. Burnam and L. Rossi
Dated: 6/16/92
MRID(s): None

CBRS No(s).: 8247
DP Barcode(s): D166382
Subject: Response to the Malathion Reregistration Standard: Product Chemistry.
From: R. Perfetti
To: L. Rossi and E. Saito
Dated: 8/13/92
MRID(s): 41409701 and 41918501

CBRS No(s).: 10694 and 10695
DP Barcode(s): D183385 and D183391
Subject: Malathion; Product Chemistry Data.
From: D. McNeilly
To: J. Edwards
Dated: 2/4/93
MRID(s): 42425901 and 42425902

CBRS No(s).: 14835
DP Barcode(s): D210228
Subject: Malathion Reregistration: Product Chemistry.
From: R. Perfetti
To: E. Saito
Dated: 1/27/95
MRID(s): None

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

40966602 A/S Cheminova (1988) Product Chemistry - Fyfanon Technical: Study No. MVF/00.01.89-Fyfanon. Unpublished updated version of MRID 79251 and 79318. 41 p.

40966603 A/S Cheminova (1988) Product Chemistry - Fyfanon Technical: Study No. MVF/00.01.89-Fyfanon. Unpublished updated version of MRID 79251 and 79318. 21 p.

41409701 A/S Cheminova (1990) Product Chemistry - Fyfanon Technical - EPA Registration Number 4787-5: 63-17 Storage Stability: Lab Project Number: MVF/00. 03. 90-FYFANON. Unpublished study. 8 p.

42265301 Friis, M. (1992) Product Chemistry--Fyfanon Technical: Lab Project Number: MVF/01.02.92/FYF-USA. Unpublished study prepared by Cheminova Agro A/S. 51 p.

42265302 Friis, M. (1992) Product Chemistry--Fyfanon Technical [Series 62]: Lab Project Number: MVF/01.02.92/FYF-USA. Unpublished study prepared by Cheminova Agro A/S. 331 p.

42425901 Friis, M. (1992) Supplement to the Report Titled: Product Chemistry - Fyfanon Technical: Series 61: Lab Project Number: MVF/10.07.92/FYF-USA. Unpublished study prepared by Cheminova Agro A/S. 14 p.

42425902 Friis, M. (1992) Supplement to the Report Titled: Product Chemistry - Fyfanon Technical: Series 62: Lab Project Number: MVF/10.07.92/FYF-USA. Unpublished study prepared by Cheminova Agro A/S. 16 p.

Case No. 0248
Chemical No. 057701

Case Name: Malathion

Registrant: Riverdale Chemical Company, Prentiss Incorporated, Cheminova Agro A/S, Amvac Chemical Corporation, Gowan Company, Drexel Chemical Company, and Micro-Flo Company.

Product(s): 91% and 95% Ts (EPA Reg. Nos. 228-274, 655-310, 4787-24, 5481-210, 10163-152, and 19713-402, and 51036-129)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product Identity and Disclosure of Ingredients	Y ³	
830.1600	Starting Materials and Manufacturing Process	N/A	
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	N/A	
830.1700	Preliminary Analysis	N/A	
830.1750	Certification of Ingredient Limits	Y ³	
830.1800	Analytical Methods to Verify the Certified Limits	N/A	
830.6302	Color	N/A	
830.6303	Physical State	N/A	
830.6304	Odor	N/A	
830.6313	Stability	N/A	
830.6314	Oxidation/Reduction	N/A	
830.6315	Flammability	N/A	
830.6316	Explosibility	N/A	
830.6317	Storage Stability	N/A	
830.6319	Miscibility	N/A	
830.6320	Corrosion Characteristics	N/A	
830.7000	pH	N/A	
830.7050	UV/Visible Absorption	N/A	
830.7100	Viscosity	N/A	
830.7200	Melting Point/Melting Range	N/A	
830.7220	Boiling Point/Boiling Range	N/A	
830.7300	Density/Relative Density/Bulk Density	N/A	
830.7370	Dissociation Constant in Water	N/A	
830.7550	Partition Coefficient (Octanol/Water)	N/A	
830.7560			
830.7570			
830.7840	Solubility	N/A	
830.7860			
830.7950	Vapor Pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. These products repackaged from EPA-registered products. All product chemistry data requirements will be satisfied by data for the technical source product(s).

² The CSFs were obtained from the product jackets for EPA Reg. No. 228-274 (CSF dated 5/31/88); EPA Reg. No. 655-310 (CSF dated 2/28/86); EPA Reg. No. 4787-24 (CSF dated 11/2/91); EPA Reg. No. 5481-210 (CSF dated 2/6/90); EPA Reg. No. 10163-152 (CSF dated 8/26/92); EPA Reg. No. 19713-402 (CSF dated 5/27/96); and EPA

Reg. No. 51036-129 (CSF dated 6/23/88).

³ We note that the CSF for each product should be modified to reflect the nominal concentration and upper and lower certified limits of the active ingredient in the product.

Case No. 0248
Chemical No. 057701

Case Name: Malathion
Registrant: Prentiss Incorporated
Product(s): 25% FI (EPA Reg. No. 655-79)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product Identity and Disclosure of Ingredients	Y	CSF 10/13/92
830.1600	Starting Materials and Manufacturing Process	N	
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	N	
830.1700	Preliminary Analysis	N/A	
830.1750	Certification of Ingredient Limits	Y	CSF 10/13/92
830.1800	Analytical Methods to Verify the Certified Limits	N	
830.6302	Color	N	
830.6303	Physical State	N	
830.6304	Odor	N	
830.6313	Stability	N/A	
830.6314	Oxidation/Reduction	N	
830.6315	Flammability	N	
830.6316	Explosibility	N	
830.6317	Storage Stability	N	
830.6319	Miscibility	N	
830.6320	Corrosion Characteristics	N	
830.7000	pH	N	
830.7050	UV/Visible Absorption	N/A	
830.7100	Viscosity	N	
830.7200	Melting Point/Melting Range	N/A	
830.7220	Boiling Point/Boiling Range	N/A	
830.7300	Density/Relative Density/Bulk Density	N	
830.7370	Dissociation Constant in Water	N/A	
830.7550	Partition Coefficient (Octanol/Water)	N/A	
830.7560			
830.7570			
830.7840	Solubility	N/A	
830.7860			
830.7950	Vapor Pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. This product is formulated from an EPA-registered product. TGAI product chemistry data requirements will be fulfilled by data for the technical source product. We note that the technical source product for the alternate formulation has been canceled.

² The CSF was obtained from the product jacket.

Case No. 0248
Chemical No. 057701

Case Name: Malathion
Registrant: Sureco Incorporated
Product(s): 45% FI (EPA Reg. No. 769-783)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product Identity and Disclosure of Ingredients	N	CSF 7/22/88
830.1600	Starting Materials and Manufacturing Process	N	
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	N	
830.1700	Preliminary Analysis	N	
830.1750	Certification of Ingredient Limits	N	CSF 7/22/88
830.1800	Analytical Methods to Verify the Certified Limits	N	
830.6302	Color	N	
830.6303	Physical State	N	
830.6304	Odor	N	
830.6313	Stability	N	
830.6314	Oxidation/Reduction	N	
830.6315	Flammability	N	
830.6316	Explosibility	N	
830.6317	Storage Stability	N	
830.6319	Miscibility	N	
830.6320	Corrosion Characteristics	N	
830.7000	pH	N	
830.7050	UV/Visible Absorption	N	
830.7100	Viscosity	N	
830.7200	Melting Point/Melting Range	N	
830.7220	Boiling Point/Boiling Range	N	
830.7300	Density/Relative Density/Bulk Density	N	
830.7370	Dissociation Constant in Water	N	
830.7550	Partition Coefficient (Octanol/Water)	N	
830.7560			
830.7570			
830.7840	Solubility	N	
830.7860			
830.7950	Vapor Pressure	N	

¹ Y = Yes; N = No; N/A = Not Applicable. This product is formulated from an EPA-registered product; however, the product listed as the technical source product is identified as an end-use product in REFS. Because no TGAI data have been submitted for the listed source product, the registrant must either identify another source product or submit all product chemistry data.

² The CSF was obtained from the product jacket.

Case No. 0248
Chemical No. 057701

Case Name: Malathion
Registrant: Cheminova Agro A/S
Product(s): 95% T (EPA Reg. No. 4787-5)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product Identity and Disclosure of Ingredients	Y ³	42265301 ⁴ , 42425901 ⁵ , CSF 7/10/92 ⁵
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Y	42265301 ⁴ , 42425901 ⁵ , No MRID Number ⁶
830.1670	Discussion of Formation of Impurities	Y	42265301 ⁴
830.1700	Preliminary Analysis	Y	40966602 , 42265302 ⁴
830.1750	Certification of Ingredient Limits	Y	40966602 , 42265301 ⁴ , 42265302 ⁴ , 42425901 ⁵ , 42425902 ⁵ , CSF 7/10/92 ⁵
830.1800	Analytical Methods to Verify the Certified Limits	Y	40966602 , 42265302 ⁴ , 42425902 ⁵
830.6302	Color	Y	40966603
830.6303	Physical State	Y	40966603
830.6304	Odor	Y	40966603
830.6313	Stability	Y ⁷	40966603
830.6314	Oxidation/Reduction	Y	40966603
830.6315	Flammability	Y	40966603
830.6316	Explosibility	Y	40966603
830.6317	Storage Stability	Y	40966603 , 41409701 ⁸
830.6319	Miscibility	Y	40966603
830.6320	Corrosion Characteristics	Y	40966603
830.7000	pH	Y	40966603
830.7050	UV/Visible Absorption	N ⁹	
830.7100	Viscosity	Y	40966603
830.7200	Melting Point/Melting Range	N/A ¹⁰	
830.7220	Boiling Point/Boiling Range	N ¹¹	40966603
830.7300	Density/Relative Density/Bulk Density	Y	40966603
830.7370	Dissociation Constant in Water	Y	40966603
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	Y	40966603
830.7840 830.7860	Solubility	Y	40966603
830.7950	Vapor Pressure	N ¹¹	40966603

¹ Y = Yes; N = No; N/A = Not Applicable.

² **Bolded** references were reviewed under CBRS No. 7469, 3/28/91, R. Perfetti; and all other references were

reviewed as noted.

³ We note that the label claim of 95% is not in agreement with the nominal concentration of the active ingredient listed on the CSF.

⁴ CBRS No. 9752, D177109, 6/16/92, R. Perfetti.

⁵ CBRS Nos. 10694 and 10695, D1883385 and D183391, 2/4/93, D. McNeilly.

⁶ CBRS No. 14835, D210228, 1/27/95, R. Perfetti.

⁷ The OPPTS Series 830, Product Properties Test Guidelines no longer require data pertaining to the stability of the TGAI on exposure to sunlight.

⁸ CBRS No. 8247, D166382, 8/13/92, R. Perfetti.

⁹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹⁰ Data are not required because the TGAI is a liquid at room temperature.

¹¹ Data reflecting analysis of the product for this property are required; published literature citations are not acceptable.